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Form 1.

(1) Here insert full name and address of Applicant or Applicants, followed by address (es).

We ALTON OCHSNER MEDICAL FOUNDATION (non-profit Louisiana Corp.)
of 1514 Jefferson Highway,
New Orleans, Louisiana,
United States of America.

(2) Here insert Title of Invention.

hereby apply for the grant of a Patent for an invention entitled (2)
SHUNT DEFECT CLOSURE SYSTEM

which is described in the accompanying COMPLETE specification.

Our address for service is Messrs. Edwd. Waters & Sons, Patent Attorneys, 50 QUEEN Street, Melbourne, Victoria, Australia.

DATED this 25th day of March 19 75

(1) Signature (s) of Applicant (s) or Seal of Company and Signatures of its Officers as prescribed by its Articles of Association.

ALTON OCHSNER MEDICAL FOUNDATION (non-profit Louisiana Corp.)

by J. O. Barnes

To:
THE COMMISSIONER OF PATENTS.

Fee 238 $

Edwd. Waters & Sons, Melbourne.

(NON-CONVENTION—Company.)

Form 7

COMMONWEALTH OF AUSTRALIA

*Patents Act 1952-1966*

# DECLARATION IN SUPPORT OF AN APPLICATION FOR A PATENT OR PATENT OF ADDITION

(1) Here insert (in full) Name of Company.

In support of the Application made by[1] Alton Ochsner Medical Foundation (non-profit Louisiana Corp.)

(2) Here insert title of Invention.

for a Patent _____ for an invention entitled[2] Shunt Defect Closure System

(3) Here insert full Name and Address of Company Official authorized to make declaration.

I,[3] Merrill O. Hines, M.D., Chairman of Board of Trustees & Patent Officer of 1514 Jefferson Highway, New Orleans, Louisiana 70121 USA

do solemnly and sincerely declare as follows:

1. I am authorized by[1] Alton Ochsner Medical Foundation

the applicant for the patent _____ to make this declaration on its behalf.

(4) Here insert (in full) Name and Address of Actual Inventor or Inventors.

2.[4] Terry D. King, M.D., 10125 Hyde Place, New Orleans, Louisiana and Noel Lang Mills, M.D., 146 Imperial Woods Drive, Harahan, Louisiana, USA

the actual inventors of the invention and the facts upon which[1] _____ Alton Ochsner Medical Foundation is entitled to make the application, are as follow:

The said[1] Alton Ochsner Medical Foundation

(5) Full Name of Actual Inventor or Inventors

is the assignee of the said[5] Terry D. King, M.D. and Noel Lang Mills, M.D.

Paragraph 2 should be completed by showing devolution of title, e.g. "The said (Name of applicant) is the assignee of the said (Name of inventor(s))".

DECLARED at New Orleans, Jefferson Parish, U.S.A.

this 11th day of March 19 75

(6) Signature

[6] Merrill O. Hines M.D.

To:

THE COMMISSIONER OF PATENTS.

Edward Waters & Sons, Melbourne.

Form 10

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952-69

# COMPLETE SPECIFICATION

(ORIGINAL)

Class Int. Class

Application Number:
Lodged:

Complete Specification Lodged:
Accepted:
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Name of Applicant: ALTON OCHSNER MEDICAL FOUNDATION,

Address of Applicant: 1514 Jefferson Highway, New Orleans, Louisiana, United States of America

Actual Inventor: TERRY D. KING, and NOEL LANG WILLS.

Address for Service: EDWD. WATERS & SONS, 50 QUEEN STREET, MELBOURNE, AUSTRALIA, 3000.

Complete Specification for the invention entitled:

SHUNT DEFECT CLOSURE SYSTEM.

The following statement is a full description of this invention, including the best method of performing it known to :- US

The present invention relates to an intravascular method and apparatus for closure of septal defects or shunts in the intravascular system or the great vessels by means of a positive mechanical structure applied by means of an outer catheter and other associated operative elements working within said outer catheter.

- General Background -

In order to gain a better understanding of the present invention and its particular application, it is noted that the heart is divided into four compartments or chambers, the two upper being the left and right atria and the two lower being the left and right ventricles. The atria are separated from each other by a muscular wall, the interatrial septum, and the ventricles by the interventricular septum.

Either congenitally or by acquisition, abnormal openings, holes or shunts can occur between the chambers of the heart or the great vessels (interatrial and interventricular septal defects or patent ductus arteriosus and aorticopulmonary window respectively), causing shunting of blood through the opening. The deformity is usually congenital, resulting from a failure of completion of the formation of the septum, or wall, between the two sides during fetal life when the heart forms from a folded tube into a four-chambered, two unit system.

These deformities can carry significant sequelae. For example, with an atrial septal defect, blood is shunted from the left atrium of the heart to the right, producing an over-load of the right heart. In addition to left-to-right

shunts such as occur in patent ductus arteriosus from the aorta to the pulmonary artery, the left side of the heart has to work harder because some of the blood which it pumps will recirculate through the lungs instead of going out to the rest of the body. The ill effects of these lesions usually cause added strain on the heart with ultimate heart failure if not corrected.

- General Discussion of Prior Art and Present Invention -

Heretofore these intracardiac or extracardiac septal defects have required relatively extensive surgical techniques for correction. In 1938 surgeons first seriously entered the field of attacking congenital heart disease when Gross reported the first ligation of a patent ductus arteriosus. Since that time rapid advances have allowed thoracic surgeons to close not only extracardiac congenital shunts but also shunts between the chambers of the heart. The modern era of extracorporeal circulation began in 1953 when Gibbon first closed an atrial-septal defect, using the heart-lung machine. To date the present method of closing intracardiac shunts, such as atrial-septal defects and ventricular-septal defects, entails the relatively drastic technique of open-heart surgery, requiring opening the chest or sternum and diverting the blood from the heart with the use of a cardiopulmonary bypass. The heart is then opened, the defect is sewn shut by direct suturing with or without a patch of synthetic material (usually of Dacron, Teflon, silk, nylon or pericardium), and the heart closed. The patient is then taken off the cardiopulmonary bypass machine, and the chest closed.

In place of direct suturing, it has been suggested that closures of interauricular septal defects could be made by means of a double "button" prosthesis, but open heart surgery

was still required. See for example "Closure of Interauricular Septal Defects" by Charles A. Hufnagel et al, The Bulletin Georgetown University Medical Center, Vol. IV, No. 5, Pp. 137-139, Feb.-Mar., 1951; which also cited Swan H.: "Experimental Closure of Interauricular Septal Defects" - Symposium of Cardiovascular Research, National Institute of Health, Jan. 21, 1950, Washington, D. C. Additional work with such a button-type prothesis in open heart surgery was also apparently done by C. P. Bailey, M.D. (see Bailey et al: "Correction of Interventricular Septal Defects," Am. Surgery, 136, 919, 1952; and Bailey: "Surgery of the Heart," Lea and Febiger, Philadelphia, Pp. 366, 1955) and by Yousif D. Al-Naaman, M.D., Department of Thoracic and Cardiovascular Surgery, University of Baghdad, Iraq.

Thus, prior to the present invention, it was only possible to repair septal defects or shunts through open-heart surgery, involving shunting the blood through an artificial pump-oxygenator (heart-lung machine) or at least supplanting the action of the heart itself (mechanical heart) while the heart is being repaired. Moreover, although excellent results have been obtained on simple septal defects by open-heart surgery, there is great risk in open-heart surgery in patients whose heart muscles have been under great strain for long periods of time.

In contrast to the relatively drastic technique of open-heart surgery, the system of the present invention closes off septal defects or shunts without the need of general anesthesia or opening of the chest. Instead the operative techniques employed in the present invention require only a small incision over a vein in the groin or neck under only local anesthesia, such as is carried out for many routine cardiac catheterizations.

Moreover, the catheter/closure system of the present invention allows a cardiologist to close a septal defect at the time of diagnostic cardiac catheterization, if desired. Because of the proposed size of the other catheter used in the present invention, this would be most reasonably carried out after the age of 4 to 5 years.

In addition to a far superior, less drastic surgical procedure, the present invention achieves this by means of a unique, permanent catheter/closure system utilizing an expandible catheter/closure structure formed by relatively inexpensive, positive mechanical elements which are relatively simple and reliable in structure and made of readily available and proven materials. In the preferred embodiment of the present invention the catheter/closure structure includes either a single expandible umbrella-like element or an opposed pair of expandible umbrella-like elements, depending on the location of the septal defect.

It is noted that the term "catheter" as used herein refers to an instrument, generally tubular in shape, which is inserted into a body cavity, naturally or surgically opened. Several different catheters have been developed in the past, either for experimental research purposes or clinical application. The Mobin-Uddin catheter is one that is used for partial occlusion of the inferior vena cava to prevent pulmonary embolization. This catheter has been described in a publication by Drs. Kazi Mobin-Uddin and James R. Jude in an article entitled "A New Catheter Technique of Interruption of the Inferior Vena Cava for Prevention of Pulmonary Embolism", The American Surgeon, Volume 35, page 889, December 1969. See also U. S. Patent No. 3,540,431 to Dr. Kazi Mobin-Uddin issued November 17, 1970. A similar catheter technique, but using a balloon obstruction instead of an umbrella type obstruction, is disclosed in the article "Experimental Balloon of the Inferior Venal Cava"

by Hunter et al, Annals of Surgery, Vol. 171, No. 3, Pp. 315-320, February 1970.

Additionally, in experimental work performed by one of the co-inventors himself, a cardiac catheter with an inflatable disc balloon for interim closure of left-to-right shunts through the ventricular septum was used. This catheter has been described in a publication by Dr. Noel L. Mills et al in an article entitled "Balloon Closure of of Ventricular Septal Defect," Supplement I to Circulation, Vols. XLIV, page I-111, May 1971. See also the article by Dr. Harold King et al entitled "Experimental Surgical Repair of Ventricular Septal Defects", SURGERY, Vol. 34, pp. 1100 - 1116, December, 1953.

Diverse examples of other expandible and/or umbrella-like elements generally used in other types of surgical applications are found in the following U.S. patents:

| Patent No. | Inventor(s) | Title | Issue Date |
|---|---|---|---|
| 2,493,326 | J. H. Trinder | "Tampon For Control of Intractable Nasal Hemorrhages" | 1/30/50 |
| 2,799,273 | V. J. Oddo | "Haemostatic Catheter" | 7/16/57 |
| 3,334,629 | B. D. Cohn | "Occulsive Device For Inferior Vena Cava" | 8/8/67 |
| 3,397,699 | G. C. Kohl | "Retaining Catheter Having Resiliently Biased Wing Flanges" | 8/20/68 |
| 3,592,184 | David H. Watkins Erwin J. Klink | "Heart Assist Method And Catheter" | 7/13/71 |
| 3,671,979 | Spyridon | "Catheter Mounted Artificial Heart Valve For Implanting In Close Proximity To A Defective Natural Heart Valve" | 6/27/72 |

However, as should be fully appreciated and understood from the detailed description of the preferred embodiments below, all of these diverse prior art catheters and umbrella-like elements, neither collectively nor individually, anticipate or make obvious the present, pioneering and far-reaching invention.

The present invention in its earlier embodiments has been experimentally tested with dogs with success, as described in the article "Nonoperative Closure of Atrial Septal Defects" by the inventors hereof which appeared in the March, 1974 issue of Surgery (Vol. 75, No. 3, pp. 383-388). With the further development work and later embodiments as described herein, the shunt defect closure system of the present invention is expected to be applied to human patients in the very near future.

Brief Description of the Drawings

For a further understanding of the nature and objects of the present invention, reference should be had to the following detailed description, taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals and wherein:

Figure 1A is a schematic illustration of the heart, partially cut away, showing the applied closure structure of the present invention closing off an atrial septal defect with two of the catheter operative elements of the catheter/closure system of the present invention being withdrawn; while

Figure 1B is similar in perspective to Figure 1A showing a typical atrial septal defect (ASD) prior to the application of the present invention.

Figure 1C is a perspective view of the left and right umbrella-like closure elements used for an ASD in their open or erected positions.

Figure 2A is a side view of the left umbrella-like closure element of the present invention in its collapsed position with the inner, central sliding sleeve shown partially in phantom lines; while

Figures 2B and 2C are side, cross-sectional and end views, respectively, of the inner, central hub of the left umbrella-like closure element of Figure 2A.

Figure 3A is a side view of the right umbrella-like closure element of the present invention in its collapsed position with the inner, central sliding sleeve shown partially in phantom lines; while

Figures 3B and 3C are side, cross-sectional and end views, respectively, of the inner, central sliding sleeve of the right umbrella-like closure element of Figure 3A.

Figure 4 is a side view of a typical strut element used in the left and right umbrella-like closure elements of the present invention.

Figure 5 is a perspective view of three of the catheter operative elements, concentrically assembled together, which are used in the method of the present invention.

Figure 6 is a side, perspective view, partially cut away, of the catheter operative elements with the left umbrella-like closure element attached to the central one with the struts thereof partially opened, portions of the umbrella-like element, particularly the covering material, not being illustrated for simplicity purposes; while

Figure 7 is similar to Figure 6 with the exception of showing the right umbrella-like closure element being affixed to the central one of the catheter operative elements and showing an additional operative element, a control disc, positioned of the proximal end of the central catheter operative element.

Figure 8 is a side view of the cone-operative element used in the method of the present invention to initially close the umbrella-like elements prior to their insertion into the outer catheter operative element.

Figures 9A through 9K are side, schematic views of the inner heart structure illustrating the sequential steps of the method of the present invention as being applied to the closing of an atrial septal defect (ASD); while

Figures 10A and 10B are right and left end views, respectively of the umbrella-like closure elements of the present invention after being applied and locked together to close off the atrial septal defect.

Figure 11 is a side, cross-sectional view of the central hub and sleeve structures of the left and right umbrella-like closure elements locked together in a male-female relationship.

Figures 12A and 12B are side, cross-sectional and side, perspective views, respectively, of two other structures allowing two other alternative methods of opening or erecting the umbrella-like structure of the right umbrella-like closure element.

Figure 13A is a schematic illustration of the heart, partially cut away, showing the applied closure structure of the present invention closing off a ventricular septal defect with an alternate method utilizing a single umbrella-like element being used; while

Figure 13B is similar in perspective to Figure 13A showing a typical ventricular septal defect (VSD) prior to the application of the present invention.

Figure 13C is a perspective view of the single umbrella-like closure element used for a VSD in its open or erected position; while

Figure 13D is a side view of the special obturator wire used in the alternative single umbrella technique.

Figure 14A is a schematic illustration of the heart, partially cut away, showing the applied closure structure of the present invention closing off a patent ductus arteriosus (PDA) using a modified right or second umbrella-like closure element with the final catheter operative element of the catheter/closure system of the present invention ready to be withdrawn; while

Figure 14B is similar in perspective to Figure 14A showing a typical patent ductus arteriosus (PDA) prior to the application of the present invention.

Figure 14C is a perspective view of the modified left and right or first and second umbrella-like closure elements used for a PDA in their open or erected positions.

Figure 15A is a side view of a second basic embodiment of the right umbrella-like element of the present invention shown mounted on the obturator wire prior to its being applied to the shunt; while

Figure 15B is a side view of the embodiment of Figure 15A as it is being applied to the shunt and being pushed to its locking position with the left umbrella-like element; while

Figure 15C is a close-up, side view of the central portions of the umbrella-like closure elements in their final, locked position.

Figures 16A and 16B are frontal views of the underside and topside respectively, of the most recent embodiment of the left umbrella-like closure element of the present invention in its open position for closing an ASD; while

Figures 17A and 17B are frontal views of the underside and topside, respectively, of the most recent embodiment of the right umbrella-like closure element in its open position used with the left unbrella-like closure element of Figures 16A and 16B.

Figure 18 is a side view of the proximal ends of the catheter operative elements used with the closure elements of Figures 16 and 17; and

Figure 19 is a side view of the distal ends of the catheter operative elements of Figure 18 without the umbrella-like closure elements attached; while

Figure 20 is a side view again of their distal ends as in Figure 19 but with the left and right umbrella-like closure elements attached and in their open positions located as they would be on opposite sides of the septum (not illustrated) and prior to being pushed and locked together.

## Detailed Description of the Preferred Embodiments

- Closure Structure And Operative Elements -

The closure structure of the present invention must be expandible, fulfilling the special requirement of being a structure which has a first, smaller physical form while it is being inserted through a blood vessel and quite a different, second, larger form when placed in its final location closing and covering the septal defect or shunt. Additionally it must meet the several stringent mechanical requirements placed upon it, must reliably open at the desired time and place, and must effect a suitable tight closure of the defect or shunt in the heart system for a long period of time without any deterioration and without producing any unwanted side-effects either on tissue or blood. Many machanical systems are conceivable to meet these requirements and a most suitable one has been developed and tested and comprises the preferred structural embodiment of the present invention, which will now for purposes of illustration and disclosure only be described in detail.

The disclosure structure of the preferred embodiment of the present invention, as illustrated in Figures 1C, 2 and 3 comprises a pair of opposed, umbrella-like elements 8, 9, a first element 8 having a central, tapered hub 84 and a second element 9 having a central, sliding sleeve 94.

The two umbrella-like closure elements 8, 9 of the preferred embodiment of the present invention have for example six material supporting struts 81, 91, respectively, each (note Figure 4). Each strut 81, 91 has for example a length of 5.35mm., with a sixty degree angle between the struts 81, 91. The struts 81, 91 are made of a radiopaque

material (not necessarily metallic), for example stainless steel, which have at the distal ends thereof small projections or barbs 83, 93, respectively, of for example 0.2 mm. length, which allow anchoring of the closure elements 8, 9 into the septum. Three holes are provided along the length of the struts 81, 91 - hinge holes 86', 96'; tie eyes 87a, 97a for raising or lowering the struts 81, 91 by means of ties or lines 7; and suture eyes 87b, 97b for attaching the umbrella material 82, 92 to the struts 81, 91. The tie holes 87a, 97a are of sufficient size to allow the ties 7 to slide easily through them.

The struts 81, 91 are attached to the umbrella-like closure elements 8, 9 through a central hub 84 and a sliding sleeve 94, respectively, made of for example stainless steel. The surfaces of the hub 84 and the sleeve 94 are grooved (note Figures 2C and 3C) in such a manner to allow the struts 81, 91, respectively, to lie superficially in their surfaces without adding to the exterior bulk of the umbrella-like structures. The struts 81, 91 are movably attached to the hub 84 and sleeve 94 by hinge ring elements 86, 96, respectively, and there are included ring-like strut keepers 87, 97, respectively, to prevent the struts 81, 91 from opening respectively, beyond ninety degrees. Each umbrella-like element 8, 9 is of small enough size to allow it to be placed within the outer, thin wall catheter 1 within which it is transported during application, as described more fully below.

Thin Dacron, Teflon, nylon, silastic, pericardium or silk, for example, routinely used to close intercardiac defects in open-heart surgery, can be used for the umbrella sheet material 82, 92, although Dacron and silk are considered preferable. The material 82, 92 should be pliable and of

sufficient strength and resiliency to open and close smoothly. Although the umbrella material 82, 92 could be fanfolded between the struts 81, 91, respectively, it is preferred that instead it be stretched or extended flat over the struts. It thus retains a certain amount of resiliency which further aids in opening the umbrellas 8, 9. The material 82, 92 is anchored centrally on the hub 84 and the sliding sleeve 94, respectively between the main body thereof and the strut keepers of 87, 97, respectively. Additionally small holes 87b, 97b are made in the struts 81, 91 so that, for example, Tycron sutures 87b', 97b' can be used to secure the umbrella material 82, 92, respectively, distally upon the struts 81, 91. Additionally, supplemental sutures 87a' can be used if desired to further secure the material 82, as the eyes 87a have not been found to be otherwise necessary.

The sliding sleeve 94 and the distal hub 84 are designed to lock securely together in opposed, facing relationship by means of an internal, central, male-female mechanism (note particularly Figure 11). A typical structure for achieving this is illustrated particularly in Figure 11 with supplemantal reference to Figures 2B and 3B. The hub 84 includes a male member 84' projecting inwardly and having a locking plateau 85 on its outer surface. This mates with the female cavity formed within the inner portion 94' of the sleeve 94. The female cavity also includes a locking groove 95 for mating with the plateau 85.

The total external diameter of the hub 84 is for example 1.3 mm., and it has been engineered with grooves 89 so that the struts 81 are recessed within the surface and do not occupy any additional space within the outer catheter 1. The hub 84 is tapered slightly to a rounded, bullet-shape configuration at the distal end to a diameter of for example approximately 0.075 mm. The proximal end of the hub 84

is relatively blunt and has a central threaded orifice 80 for mating with the threaded end 31 of the obturator wire 3, described more fully below. The hub 84 can be for example 3 mm. in length.

Although it has not been found to be necessary, the central sliding sleeve 94 of the right umbrella 9 could have a flared or conical distal end in order to center it automatically with respect to the hub projection 84' as a prelude to sliding up over it and along it to the locked position. The bore 90 of the right sleeve 94 is considerably larger than the diameter of the obturator guide wire 3, described below, to allow for free movement thereon.

The operative elements of the closure catheter system of the preferred embodiment of the present invention comprise several parts: an outer catheter 1; an inner, locking catheter 2; an obturator guide sire 3; a loading cone 4; a manipulating "T"-piece 5; and a tie retracting and control disc 6 with a series of manipulating ties 7. Note particularly Figures 5, 7, 8 and 9J.

The outer, thin wall catheter 1, for example a #24 French size, is of sufficient length (for example 80-105 cm.) to allow its manipulation into the heart area. The outer catheter 1 can be made from thin wall, woven Dacron or preferably polyvinyl material and has a gentle curve at the cardiac end to allow easy manipulation through a septal defect in the cardiac area.

As shown in Figure 5, inside the outer, thin wall catheter 1 is a second, radiopaque, inner catheter 2 which could be for example a #5 French size catheter of polyvinyl. It should be of sufficient length (for example 90-110 cm.) to protrude from the proximal end of the outer catheter 1 and has a rounded, cone-shaped distal hub 21 (note Figure 9C). The inner catheter 2 should be of a size to be quite mobile through the outer catheter 1.

Passing through the inner catheter 2 is an obturator guide wire 3 which can be for example 1.1 mm. or less in diameter and have a length of for example 200-350 cm. A removable, proximal "T"-piece 5 (note Figure 9J) is used for rotational manipulation of the obturator wire 3. The "T"-piece is locked to the obturator wire 3 and is easily removable therefrom by means of a locking set screw 51 going through the central hub element 53. For gripping purposes an extention arm 52 is provided.

The cardiac or distal end 31 of the obturator wire 3 is threaded for approximately 1 mm. so that it may be screwed and unscrewed into the distal hub 84 of the left closing umbrella 8. The obturator wire 3 should be of sufficient flexibility to allow easy manipulation and can be for example made of a fixed core stainless steel spring material.

As shown in Figure 7, a control disc 6 is provided for ease in manipulating and controlling the ties or suture lines 7. The disc can be made of stainless steel and is placed on the exterior, proximal portion of the obturator wire when needed. A series of hole pairs 61 are provided about the periphery of the disc for holding the ties 7. Although not illustrated, the holes 61 could be numbered or coded to the particular struts involved and an additional pair of holes can be provided for the retracting ties 7'. The ties 7, 7' can be made of for example monofilament nylon or 3-0 silk.

The final operative element is the loading cone 4, illustrated in Figure 8. The loading cone 4 is provided to assist in the easy loading or insertion of the umbrella-like elements 8, 9 into the outer catheter 1. For example, as shown in Figure 8, the left umbrella 8, threaded onto

the distal end 31 of the obturator wire 3 and in its open or partially opened position, is first inserted through the loading cone 4 which leads into the outer catheter 1. The cone 4 serves to close the umbrellas 8, 9 making them of a small enough size for insertion into the outer catheter 1.

The distance across the total closure structure from hub tip to sleeve tip (note Figure 9K) once locked in place is only approximately 3.5 mm., elements can be produced in diameter sizes of for example 10 mm., 15 mm., 20 mm., 25 mm., 30 mm. and 35 mm. as desired or needed.

Thus, an effective and reliable embodiment is provided for a typical closure structure and associated operative elements. Of course many, other structures are possible, the variations being practically limitless. For example, rather than dual, opposed umbrellas, a single umbrella could be used as described more fully below with respect to the repair of a ventricular septal defect.

Additionally the means of expanding or opening the umbrella can be easily varied. For example as generally shown in Figure 12A the struts 91' of the right umbrella can be machanically forced open by appropriate shoulder and flange elements 97' as the sleeve 94a is pushed and locked into the hub 84. Alternatively, as generally illustrated in Figure 12B, the struts 91* could be made of resilient, flexible material so that the umbrella will inherently or automatically open once it emerges from the outer catheter (note the movement of the phantom lined strut).

An additional, very effective, exemplary embodi-

ment of the right umbrella is shown in Figures 15A-C in which the necessity of a tie wire system is eliminated. The umbrella 209 is similar in general structure to the right umbrella 9 except that in place of the tie wire system there is included a set of elevating struts 291' hingedly attached between the regular umbrella struts 291 and the elevating sleeve 294'. As shown in Figure 15B, as the elevating sleeve 294' comes into contact with the hub 84, the umbrella becomes erected under the continuing pressure of the inner catheter 2 until it is locked into place as shown in Figure 15C.

Finally, although an umbrella-type structure is thought to be particularly effective, other expansion systems, i.e., the elements which initially have a relatively small size for insertion and positioning and which then expand to a relatively large size when in place, are possible and likewise nearly limitless. For example, in place of the umbrella elements, a balloon(s) or other inflatable structure(s) could be used.

- Typical Method of Application -

For purposes of illustration and disclosure purposes only, the method of application of the present invention will now be described in detail with respect to the closing of an atrial septal defect (ASD) with particular reference to Figures 1A-C and 9A-K.

In order to gain access to the heart, an incision is made in either the right or left groin under local anesthesia, and the femoral vein isolated. Standard catherization techniques are then utilized to confirm the presence of the ASD such as the one shown in Figure 1B. Once confirmed, sizing of the ASD is then achieved by means of special but standard balloon catheters, and the appropriate size of umbrella-like closure elements 8, 9 are selected.

The initial closing/catheter assembly (note Figure 5), i.e. elements 1, 2 and 3, the latter having the left umbrella 8 attached to its threaded end 31, is then inserted via the femoral vein into the heart under continuous flouroscopic control into the right atrium. With further advancing of the catheter assembly, it is placed in the left atrium (note Figure 9A).

By manipulating the obturator wire 3, the distal hub 84 carrying the collapsed left umbrella 8 is advanced beyond the outer, thin wall catheter 1 into the left atrium (Figure 9B). Once the left umbrella 8 is pushed beyond the tip of the outer, thin wall catheter 1, the umbrella 8 is initially unfolded by pushing the inner catheter 2 against the struts 81 and holding fast the obturator wire 3 (Figure 9C), expanding the umbrella out in excess of the diameter of the outer catheter 1.

Then by pulling gently on the obturator wire 3, the umbrella 8 is pulled against the distal end 11 of the outer catheter 1, opening the umbrella 8 to its full ninety degree position (Figure 9D). The outer catheter 1 is then pulled back into the right atria and the umbrella 8 pulled snugly against the left atrial septum, with the distal barbs 83 being anchored against the septum (Figure 9E).

Once the left umbrella 8 is firmly fixed, the inner catheter 2 is withdrawn and removed and the right umbrella 9 slid unto the obturator wire 3 and loaded into the outer catheter 1 with the retraction ties 7 and retracting ties 7' in place on the struts 91 and sleeve 94, respectively, and the disc 6 (note Figure 7). The collapsed right umbrella 9 is then pushed through and out the outer catheter 1 by means of the inner catheter 2 into the right atrium and positioned just superior to the inferior vena cava and right atrial junction (Figure 9F). At this point the outer catheter 1 is withdrawn to allow the right umbrella 9 to lie freely upon the obturator guide wire 3 within the body of the right atrium.

As the inner catheter 2 is advanced and traction maintained on the elevating ties 7 and on the retracting sutures or ties 7', the right umbrella 9 is opened (Figure 9G) and pushed snugly against the inter-atrial septum by means of the inner catheter 2. By fluoroscopic monitoring, it can be determined that all six struts 91 are at right angles. The inner catheter 2 is pushed further forward, forcing the sliding sleeve 94 of the right umbrella 9 to slide onto the left umbrella hub 84, locking the two together (Figure 9H). A clicking sensation is felt through the obturator wire 3, and a click can be heard as the umbrellas 8, 9 are

locked into place. Once in place the umbrellas 8, 9 are tugged gently with the obturator guide wire 3 to assure stability.

Once the umbrellas 8, 9 are locked in place, the obturator wire 3 can be unscrewed from the distal hub 84, using the "T"-piece 5 on the proximal portion of the obturator wire 3, thus leaving in place the distal hub 84 with the right and left umbrellas 8, 9 locked in place (Figure 9J). The obturator guide wire is thus unthreaded with the aid of the "T"-piece 5 from the left umbrella hub 84 and removed from the heart with the outer and inner catheters 1, 2 (Figure 9K). Following this, the outer, thin wall catheter 1, the inner catheter 2 and the obturator wire 3 are completely withdrawn from the body.

Following installation of the closure structure, a diagnostic venous catheter can be introduced for the appropriate angiograms, dye curves and hydrogen electrode studies to confirm the effectiveness of the closure of the septal defect. The closure structures 8, 9 should be covered by endocardium within six to eight weeks, and be thereby integrated into the heart's structure.

After completion of the operation, the vein and inguinal incision are closed.

- Additional Methods of Application -

For purposes of further illustration and disclosure, the method of application of the present invention will now be described in some detail with respect to the closing of a ventricular septal defect (VSD) with particular reference to Figures 13 A-C.

In order to gain access to the heart, an incision is made in the right neck over the external or internal juglar vein under local anesthesia. The jugular vein is isolated and venotomy is made for insertion of the outer catheter 1. Standard catherization techniques are then utilized to confirm the presence of the VSD such as the one shown in Figure 13 B. Once confirmed, sizing of the VSD is then achieved by means of special but standard balloon catheters, and the appropriate size of the left umbrella-like closure element 8' is selected.

The outer catheter is inserted into the vein and subsequently passed into the right heart and manipulated across the ventricular septal defect into the left ventricle. Its position can be documented by obtaining an oxygen sample or passing an NIH catheter through the outer catheter into the left ventricle and doing a hand injection.

The proper size umbrella 8' similar in structure to the left umbrella 8 described above is loaded into the outer catheter and passed into the left ventricle and opened by using the inner catheter in the same manner as is carried out in closing the atrial septal defect as described above. The opened umbrella 8' is pulled snugly against the left side of the interventricular septum adjacent to the ventricular septal defect.

The outer and inner catheters are then removed from the body, leaving the obturator wire 3, and Silastic tubing 3' is passed over the guide wire 3 and subsequently into the heart

to entirely cover the exposed guide wire 3.

By maintaining general pressure on the guide wire 3, the umbrella 8' is held tightly against the left side of the interventricular septum and thus closes the interventricular septal defect. The umbrella 8' is maintained in place by the barbs on the tips of the struts (like those described above) and by the obturator wire 3. Additionally the internal blood pressure system, which is greater in the left ventricle than the right (typically 90 min. Hg vs. 30 min. Hg), serves to help maintain the umbrella 8' over the VSD, closing it off.

The Silastic material 3' and the guide wire 3 are cut off at the appropriate lengths to allow anchoring them in the tissues of the right neck within the jugular vein. The incision is closed, and periodic checks are made of the umbrella 8' over the subsequent 15 minutes by fluoroscopy.

The patient is anticoagulated prior to the installation of the ventricular closing umbrella and is maintained on anticoagulation therapy for several weeks. After about six to eight weeks and the umbrella 8' has been endothelialized, an incision is again made over the proximal end of the Silastic material 3' and guide wire 3 (quite close to the original incision in the neck). The guide wire 3 and Silastic outer covering 3' is isolated, and with the use of the "T"-piece 5 on the proximal end of the obturator wire 3, the latter is unscrewed and removed from within the heart and vascular system. The Silastic material 3' is of course removed simultaneously with the guide wire 3, and the incision closed leaving the VSD permanently closed.

Thus, the ventricular septal defect is closed with the use of only a single umbrella 8' with temporary anchoring by the guide wire 3 covered with the Silastic material 3 to prevent clotting and embolization.

To close a patent ductus arteriosus (PDA), for example like that shown in Figure 14B, the same analogous method discussed with respect to the ASD of Figure 1B and the steps of Figures 9 A-K can be used. However, because of the longer distance between the left and right outer walls of the PDA, modified aortic and pulmonary umbrella elements 108, 109 are used in place of the left and right umbrella elements 8, 9. The main modification is to extend further out the male member of the aortic umbrella 108 or alternatively the female member 194 (as illustrated in Figure 14C). Otherwise the structure of the umbrellas 108, 109 can be identical to that disclosed in detail above with respect to the umbrellas 8, 9.

Finally, it is noted that it is advantageous to use the closure structures of the present invention even when open-heart surgery is necessary, as for example in the case of small babies. In such cases, the closure structures of the present invention can be applied through the open heart in a matter of a few minutes as opposed to the typical thirty to forty minutes usually taken with standard suturing of the shunt as practiced in the prior art.

- Latest Septal Defect Closure System -

The first described embodiment of the closure elements and the catheter operative elements and its method of application described in detail with respect to Figures 1C - 11 were initially developed and experimentally tested with dogs with success. Further development work has produced the embodiment of Figures 16A-20 which is expected to be applied to human patients in the very near future and which will now be described in detail.

As shown in Figures 16A & B and 17A & B, for an ASD there is provided two unbrella-like closure elements, a left one 308 and a right one 309, each having for example six material supporting struts 381, 391, respectively.

The struts 381, 391 are made of a radiopaque material (not necessarily metallic), for example stainless steel, and as illustrated are initially flat in the radial plane and then are twisted ninety degrees so that they are then flat in the plane of the septum. The struts 381, 391 are hingedly attached to a central hub 384 and a sliding sleeve 394, respectively, also made of for example stainless steel. The surfaces of the hub 384 and the sleeve 394 are grooved to hold the struts 381, 391.

As noted above, thin Dacron, Teflon, nylon, silastic, pericardium or silk, for example, can be used for the umbrella sheet material 382, 392 which is sutured to the struts 381, 391, respectively.

The sliding sleeve 394 and the distal hub 384 are designed to lock securely together in opposed, facing relationship by means of an internal, central, male-female mechanism, as described above with respect to the previously described embodiments (note for example Figure 11).

Like the embodiment of Figure 12B, the struts 381, 391 are designed to be self-opening by the use of a resilient structure. In the embodiment of Figures 16 and 17, this inherent resiliency is provided by the addition of a thin, resilient, springy ring 387, 397, of for example silastic material attached to the struts which causes them to automatically spring out when they are no longer constrained or under restraint. Suitable dimensions for the ring 387, 397 for an umbrella-like closure element of two cm. diameter is a ring having an outer diameter of 8 mm. and a thickness of 0.5 mm. The resilient members 387, 397 can take on various forms besides a ring, such as for example a disc or individual arms (not illustrated).

As before with respect to the embodiment of Figure 5, the operative elements of the closure catheter system for the umbrella-like closure elements of Figures 16 and 17 comprise several parts: (note Figures 18-20) an outer catheter 301, an inner, locking or right atrial catheter 302, and an obturator wire 303. However, in this later embodiment, the outer catheter 301 includes at its distal end a housing capsule 310 which is used to house both closure elements 308, 309 as the catheter is inserted into the body in juxtaposition to the septal defect to be closed. Additionally the distal end of the inner, locking catheter includes a terminal threaded portion 321 (in place of the distal hub 21 of inner catheter 2) which mates with a similarly threaded female orifice in the sliding sleeve 394, which allows positive, detachably fixed movement of the right umbrella-like element 309 on the end of the inner catheter 302. At the proximal end of the inner catheter 302, there is provided a "manipulating-stop" hub 302' which prevents the proximal end of the inner catheter from going into the outer catheter 301 and allows the inner catheter 302 to be easily manipulated for the twisting, pushing or pulling thereof.

As before, the left umbrella-like element 308 is detachably fixed by threaded engagement to the threaded portion 331 on the distal end of the obturator wire 303. As illustrated in Figure 19, the terminal distal section of the obturator wire 301 can include a built-up portion 301! for strengthening purpos

The method of application of the embodiment of Figures 16 - 20 is similar to that disclosed with respect to Figures 9A - 9K except that the closed umbrella-like closure elements 308, 309 fastened to the distal ends of the obturator wire 303 and the inner catheter 302, respectively, are both initially placed in line in the distal capsule 310. The loaded capsule 31 then is inserted through the body in juxtaposition to the septal defect in the position analogous to that shown in Figure 9A. The left closure element 308 is pushed out of the capsule 310 until it is clear thereof, at which point the struts 381 automatically open under the spring action of the resilient ring 387. The outer catheter 301 is then pulled back into the right atria, and the open closure element 308 gently pulled snugly against the left atrium septum (analogous to the action illustrated in Figure 9E).

Once the left closure element 308 is firmly in positio the right closure element 309 by means of the inner catheter 302 is moved out of the distal capsule 310 until it is clear thereof at which point the struts 391 automatically open under the spring action of the resilient ring 397. The inner catheter 302 with the open right closure element 309 on the end thereof is pushed further forward, riding over the obturator wire 303 and forcing the sliding sleeve 394 of the right closure element 309 to slide onto the left closure element hub 384, locking the two together (analogous to the action illustrated in Figure 9H).

Once the umbrella-like elements 308, 309 are locked in place, the obturator wire 301 and the inner catheter 302 can be unscrewed from them and, with the outer catheter 301, completely withdrawn from the body. To insure that the closure elements 308, 309 are securely locked, the inner catheter 302 is unscrewed first and the two umbrella-like structures 308, 309 moved to-and-fro by means of the obturator wire 303 and the action viewed by flouroscopy.

Other than the differences in structure and method outlined above, the two embodiments are at least generally the same and reference is had to the more detailed description of the embodiment of Figures 10-11 for further detailed understanding of the embodiment of Figures 16-20.

Thus atrial septal defects (Figure 1) and in similar fashion ventricular septal defects (Figure 13) and great vessel shunts (Figure 14) are closed by non-invasive techniques. The closure catheter system of the present invention is efficient and with proper caution is safe.

From past experience with cardiac surgery, stainless steel, particularly of the 300 series, which is the preferred materials for all structural parts remaining in the heart, and materials such as Dacron, Teflon, nylon, percardium, Silastic and silk can be permanently inserted within the heart and tolerated without adverse effects. It is estimated that the heart will endothelialize the closure elements within six to eight weeks as occurs after standard shunt closures using open-heart surgery.

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the embodiments herein detailed in accordance with the descriptive requirements of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting sense.

What is claimed as invention is:

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A shunt defect closure apparatus for closing off a shunt defect in the septum of for example the intravascular system comprising:

mechanical expansion means having an initial size substantially smaller than the diameter of the shunt defect to be closed during its preliminary handling and a final size substantially larger than the diameter of the shunt defect when it is positioned over and across the shunt defect to permanently close it off after being expanded to its larger size, said expansion means comprising a dual set of umbrella-like structures for placement on opposite sides of the shunt defect, the umbrella-like structures having central hub means for connecting said dual set of umbrella-like structures together through the shunt, each said umbrella-like structures including a series of relatively hard, strut-like members emanating out from said central means in at least a generally perpendicular, radial direction when said expansion means is in its final size and in at least a generally parallel, axial direction when said expansion means is in its initial size; and

operative means removably connected with said expansion means for at least temporarily holding the said expansion means on to the shunt defect after at least one of said umbrella-like structures has been expanded out to its final size.

2. The apparatus of Claim 1 wherein said umbrella-like structure comprises a series of supporting struts with flexible material suspended between said struts, said structs being moveably attached to a centrally located support element for movement from a closed position to an open position or vice-versa.

3. The apparatus of Claim 1 wherein said operative means includes an obyurator wire having attaching means at its distal end for temporarily attaching said obturator wire to one of said umbrella-like structures.

4. The apparatus of Claim 3 wherein said operative means further includes an outer catheter serving as a conduit for placing both said umbrella-like structures through the body adjacent to the shunt, said outer catheter having a diameter substantially greater than said obturator wire, said one of said umbrella-like structures being transported through said outer catheter by means of being mounted on the distal portion of said obutrator wire and pushing said obturator wire with said one of said umbrella-like structures means thereon through said outer catheter.

5. The apparatus of Claim 1 wherein said operative means includes an obturator wire having attaching means at its distal end for temporary connection to one of said umbrella-like structures and wherein said first one of said umbrella-like structures has a central hub having a connection means for temporary connection to said obturator wire; and wherein said second umbrella-like structure has a central sleeve which can slide over said obturator wire, said central hub and said central sleeve having locking means for locking them together in opposing fashion when on opposite sides of the shunt.

6. The apparatus of Claim 5 wherein said locking means comprises a male-female connection between said central hub and said central sleeve, the exterior of said connection means of said central hub forming the male member and the interior of said sleeve forming at least in part the female orifice.

7. The apparatus of Claim 6 wherein said male member includes a projection of its mating surface and said female orifice includes an

indentation for further mating with said projection and locking the hub and sleeve together.

8. The apparatus of Claim 1 wherein each said umbrella-like structures includes an expanse of relatively flexible material extending between said strut-like members to thereby at least substantially close off the spaces between said strut-like members.

9. The apparatus of Claim 1 wherein said umbrella-like structures have their undersides in opposing relationship to each other and said strut-like members are made of resilient material and resiliently bear inwardly toward the opposing umbrella-like structure, thereby securing the opposing umbrella-like structures to the septum.

10. The apparatus of Claim 1 wherein said strut-like members include at their distal tips barb-like members emanating from their underside in a direction at least generally perpendicular thereto for bearing against the septum when each of said umbrella-like structures is moved toward the septum.

11. The method of closing off a shunt defect in the septum of for example the intravascular system comprising the following steps:

a) providing a shunt defect closure structure for closing off the shunt defect comprising mechanical expansion means having an initial size substantially smaller than the diameter of the intravascular shunt defect to be closed and a final size substantially larger than the diameter of the shunt defect for positioning over and across the shunt defect to permanently close it off after being expanded to its larger size, said expansion means comprising at least one umbrella-like structure for placement on the side of the shunt, said umbrella-like structure including a central hub having a series of relatively hard, strut-like members emanating out from said central hub in at least a generally parallel, axial direction when said expansion means is in its initial size and a generally perpendicular, radial

8. The apparatus of Claim 1 wherein each said umbrella-like structures includes an expanse of relatively flexible materia extending between said strut-like members to thereby at least substantially close off the spaces between said strut-like members

9. The apparatus of Claim 1 wherein said umbrella-like structures have their undersides in opposing relationship to each other and said strut-like members are made of resilient material and resiliently bear inwardly toward the opposing umbrella-like structure, thereby securing the opposing umbrella-like structures to the septum.

10. The apparatus of Claim 1 wherein said strut-like members include at their distal tips barb-like means emanating from their underside in a direction at least generally perpendicular thereto for bearing against the septum when each of said umbrella-like structures is moved toward the septum.

11. The method of closing off a shunt defect in the septu of for example the intravascular system comprising the following steps:

a) providing a shunt defect closure structure for closing off the shunt defect comprising mechancial expansion means having an initial size substantially smaller than the diameter of the intravascular shunt defect to be closed and a final size substanti larger than the diameter of the shunt defect for positioning over and across the shunt defect to permanently close it off after bein expanded to its larger size, said expansion means comprising at least one umbrella-like structure for placement on the side of the shunt, said umbrella-like structure including a central hub having a series of relatively hard, strut-like members emanating out from said central hub in at least a generally parallel, axial direction when said expansion means is in its initial size and a generally perpendicular, radial direction when said expansion means is in its final size, said umbrella-like structure being made of a tissue compatible material which can be endothelialized into the septum; and operative means associated with said expansio

direction when said expansion means is in its final size, said umbrella-like structure being made of a tissue compatible material which can be endothelialized into the septum; and operative means associated with said expansion means for at least temporarily holding the said expansion means on to the shunt defect;

b) making an opening in the body;

c) introducing said closure structure while in its smaller size in proximity to the shunt to be closed by means of said opening;

d) expanding said umbrella-like structure of said closure structure to its larger size by expanding out said strut-like members;

e) permanently positioning and attaching said umbrella-like structure of said closure structure while in its larger size over and across the shunt, closing the shunt;

f) allowing said umbrella-like structure of said closure structure to become endothelialized, furtner closing off the shunt; and

g) ultimately closing off said opening; whereby the shunt is permanently closed by substantially non-invasive or at least limitedly evasive techniques and without the substantial suturing of the shunt as practiced in the prior art.

12. The method of Claim 11 wherein in step (b) the opening in the body is made by making a relatively small, minor incision to gain access to a vein or artery of the blood circulatory system; and wherein in step "c" the introduction is made through said vein or artery.

13. The method of Claim 11 wherein in step "a" in providing said expansion means there is further included the providing of a second umbrella-like structure having the same claimed features as the first umbrella-like structure for placement on the opposite side of the shunt from said first umbrella-like structure and steps "c" through "c" inclusive are each repeated for said second umbrella-like structure.

14. The method of Claim 13 wherein in step "a" said operative means are provided by providing an outer catheter having a cross-sectional area smaller than the shunt and an obturator wire having a diameter substantially smaller than said outer catheter; and wherein in step "b" the oepning in the body is made by making a relatively small minor incision to gain access to a vein or artery; and wherein in step "c" the introduction is made through said vein or artery and includes the following steps:

i) inserting said outer catheter through the incision into and through the vein/artery until its distal end is in juxtaposition to the shunt and, for said first umbrella-like structure, is passed through the shunt but, for the second umbrella-like structure, is located on the proximal side of the shunt; and

ii) moving said umbrella-like structures out of the distal end of said outer catheter.

15. The method of Claim 14 wherein in step "c" there is further included in sub-step "ii" the steps of:

attaching said first umbrella-like structure to the distal end of saidobturator wire and inserting the obturator wire with said first umbrella-like structure attached thereto in its initial size into and through the outer catheter until said first umbrella-like structure has emerged out of the distal end of said outer catheter;

and wherein in step "e" the underside of said first umbrella-like structure is pulled against the distal side of the septum.

16. The method of Claim 14 wherein in step "a" in providing said second umbrella-like structure there is further included the provising of a central sleeve with a central orifice having a diameter greater than said obturator wire but less than said outer catheter; and wherein in step "c" there is further included in sup-step "ii" the

steps of:

sliding said central sleeve of said second umbrella-like structure over said obturator wire and passing said second umbrella-like structure through said outer catheter while in its initial size until said second umbrella-like structure has emerged out of the distal end of said outer catheter;

and wherein in step "e" the underside of said second umbrella-like structure is pushed against the proximal side of the septum.

17. The method of Claim 16 wherein in step "a" additional operative means are provided by providing a second, inner catheter having a diameter smaller than said outer catheter and having a central longitudinal opening along its length of a diameter larger than the diameter of said obturator wire and being slidable thereon and having a tip at its distal end; and wherein, in the step "e" for said second umbrella-like structure, is pushed against the proximal side of the septum by pushing the tip of said inner catheter against the central sleeve of said second umbrella-like structure.

18. The method of Claim 17 wherein in step "a" the central hub of said first umbrella-like structure is provided with a centrally located, locking male member, the center of which serves as the connecting means for attaching the central hum to the distal end of the obturator wire; and wherein, in the step "e" for said second umbrella-like structure, said inner catheter is used to push the central sleeve of said second umbrella-like structure so that its orifice, which then serves also as a female member, is pushed into the locking male member of said first umbrella-like structure, locking the two umbrella-like structures together.

19. The method of Claim 17 wherein in step "a" the strut-like members of said second umbrella-like structure are provided with a set

of elevating struts hingedly connected at one end to the strut-like members at a point removed from said central sleeve and at the other end to a centrally located, leading and elevating member; and wherein, in the step "d" for said second umbrella-like member, said second umbrella-like structure is expanded by pushing said central sleeve toward said elevating member by means of said inner catheter, causing said elevating struts to push said strut-like members out away from said central sleeve.

20. The method of claim 17 wherein in step "a" the strut-like members of said umbrella-like structures are provided with resilient, flexible means for automatically and inherently expanding said umbrella-like structures in step "d" once they emerge from said outer catheter.

21. A shunt defect closure apparatus for closing off a shunt defect in the septum of for example the intravascular system comprising:

mechanical expansion means having an initial size substantially smaller than the diameter of the shunt defect to be closed during its preliminary handling and a final size substantially larger than the diameter of the shunt defect when it is positioned over and across the shunt defect to permanently close it off after being expanded to its larger size, said expansion means comprising at least one umbrella-like structure for placement on one side of the shunt, said umbrella-like structure having central hub means of at least a generally cylindrical shape for having pressure applied to it along its longitudinal axis for forcing the distal end portions of the underside of said umbrella-like structure against the septum to at least partially close the shunt, said umbrella-like structure being of a material that will be endothelialized into the septum; the main surface of the umbrella-like structure in its expanded size being at least substantially perpendicular and radial to said

central hub means and hence to the central axis of the shunt; and operative means removably connected with said expansion means for at least temporary holding said expansion means on to the shunt defect.

22. The apparatus of Claim 21 wherein the underside of said umbrella-like structure has on its distal portions bearing means for bearing against the septum when said umbrella-like structure is moved toward the septum, the bearing direction being generally perpendicular to the main surface of said umbrella-like structure and hence parallel to the central axis of the shunt.

23. The apparatus of Claim 21 wherein said umbrella-like structure in its final size includes a series of relatively hard strut-like members radially emanating out from said extended central means in a direction at least generally perpendicular thereto, the distal tips of said strut-like members including barb-like structures emanating in a direction at least generally perpendicular thereto, said barbs serving as said bearing means.

24. The apparatus of Claim 21 wherein said umbrella-like structure includes an expanse of relatively flexible material extending between said strut-like members to thereby at least substantially close off the spaces between said strut-like members.

25. The apparatus of Claim 21 wherein said strut-like members are made of resilient material and resiliently bear inwardly toward the septum when the umbrella-like structure is in its final size, thereby securing the umbrella-like structure to the septum.

26. A shunt defect closure apparatus for closing off a shunt defect in the septum of for example the intravascular system comprising:

mechanical expansion means having an initial size substantially smaller than the diameter of the shunt defect to be closed during its preliminary handling and a final size substantially larger than the diameter

of the shunt defect when it is positioned over and across the shunt defect to permanently close it off after being expanded to its larger size, said expansion means comprising at least one expansion structure being of a material that will be endothelialized into the septum and having an extended, main body with a facing side for contacting the septum surface around the shunt and being extended at least in part in a direction at least generally parallel to the septum surface, and extended central hub means centrally located within said main body and being extended in a direction at least generally perpendicular to the septum surface for having pressure applied to it along its extended direction for forcing the distal, end portions of the facing side of said expansion structure against the septum to at least partially close the shunt, the facing side of said expansion structure having on its distal portions anchoring means for anchoring said expansion structure to the septum when said expansion structure is forced against the septum, said anchoring means comprising projections extending at least partially in a direction parallel to said extended central means and hence parallel to the central axis of the shunt and perpendicular to the septum surface.

27. The apparatus of Claim 26 wherein said expansion structure is an umbrella-like structure having a series of relatively hard strut-like members radially emanating from said extended central means, and having projections at their distal ends, said projections being barb-like structures emanating in a direction at least generally perpendicular to the emanating direction of said strut-like members.

28. The apparatus of Claim 27 wherein said umbrella-like structure includes an expanse of relatively flexible material extending between said strut-like members to thereby at least substantially close off the spaces between said strut-like members.

29. The apparatus of Claim 27 wherein said strut-like members are made of resilient material and resiliently bear inwardly toward the

septum when the umbrella-like structure is in its final size, thereby securing the umbrella-like structure to the septum.

30. The method of closing off a ventricular septal defect in the intravascular system comprising the following sequential steps:

a) providing a ventricular septal defect closure structure for closing off the ventricular septal defect comprising mechanical expansion means having an initial size substantially smaller than the diameter of the intravascular shunt defect to be closed and a final size substantially larger than the diameter of the septal defect for positioning over and across the septal defect to permanently close it off after being expanded to its larger size, said expansion means being made of a tissue compatible material which can be endothelialized into the septum; and operative means associated with said expansion means for at least temporarily holding the said expansion means on to the defect, said operative means including an obturator wire having attaching means at its distal end for temporarily attaching said obturator wire to said expansion means;

b) making a relatively small, minor incision or opening in the body and into a vein having access to the ventricle with the defect;

c) introducing the obturator wire with said closure structure attached to its distal end while in its smaller size into said opening and through the septal defect;

d) expanding said expansion means of said closure structure to its larger size;

e) using said obturator wire to position and attach said expansion means of said closure structure while in its larger size over and across the far side of the septal defect, closing the septal defect;

f) closing off said opening in the body with said obturator wire still attached to said expansion means;

g) allowing said expansion means of said closure structure to become endothelialized over a substantial period of time, further closing off the septal defect;

h) reopening the opening in said body and removing said obturator wire; and

i) permanently closing off said opening, whereby the shunt is permanently closed by substantially non-invasive or at least limitedly evasive techniques and without the substantial suturing of the shunt as practiced in the prior art.

31. The method of Claim 29 wherein in step "b" the vein used for the opening is the external or internal jugular vein and the incision is made in the neck.

32. A shunt defect closure apparatus for closing off a shunt defect in the septum of for example the intravascular system comprising:

mechanical expansion means having an initial size substantially smaller than the diameter of the shunt defect to be closed during its preliminary handling and a final size substantially larger than the diameter of the shunt defect when it is positioned over and across the shunt defect to permanently close it off after being expanded to its larger size, said expansion means comprising a dual set of umbrella-like structures for placement on opposite sides of the shunt defect, the umprella-like structures having central hub means for connecting said dual set of umbrella-like structures together through the shunt, each said umbrella-like structures including a series of relatively hard, strut-like members emanating out from said central means in at least a generally perpendicular, radial direction when said expansion means is in its final size and in at least a generally parallel, axial direction when said expansion means is in its initial size said umbrella-like structures being provided with resilient, flexible means for automatically expanding said umbrella-like structures from their initial sizes to their final sizes when said umbrella-like structures are under no radial restraint; and

operative means removably connected with said expansion means for at least temporarily holding the said expansion means on to the shunt defect after at least one of said umbrella-like structures has been expanded out to its final size.

33. The apparatus of Claim 32 wherein said umbrella-like structure comprises a series of supporting struts with flexible material suspended between said struts, said struts being moveable attached to a centrally located support element for movement from a closed

position to an open position or vice-versa.

34. The apparatus of Claim 33 wherein said supporting struts are themselves made of resilient, flexible material, thereby inherently providing said resilient, flexible means.

35. The apparatus of Claim 33 wherein said resilient, flexible means comprises a resilient, flexible structure which is separate from said supporting struts but is attached thereto.

36. The method of closing off a shunt defect in the septum of for example the intravascular system comprising the following steps:

a) providing a shunt defect closure structure for closing off the shunt defect comprising mechanical expansion means having an initial size substantially smaller than the diameter of the intravascular shunt defect to be closed and a final size substantially larger than the diameter of the shunt defect for positioning over and across the shunt defect to permanently close it off after being expanded to its larger size, said expansion means comprising at least one umbrella-like structure for placement on the side of the shunt, said umbrella-like structure including members emanating out from said central hub in at least a generally parallel, axial direction when said expansion means is in its initial size and a generally perpendicular, radial direction when said expansion means is in its final size, said umbrella-like structure including resilient, flexible means for automatically expanding said umbrella-like structure is under no radial restraint, said umbrella-like structure being made of a tissue compatible material which can be endothelialized into the septum; and operative means associated with said expansion means for at least temporarily holding the said expansion means on to the shunt defect;

b) making an opening in the body;

c) introducing said closure structure while in its smaller size under radial restraint in proximity to the shunt to be closed by means

of said opening;

d) expanding said umbrella-like structure of said closure structure to its larger size by automatically expending out said strut-like members by eliminating said radial restraint;

e) permanently positioning and attaching said umbrella-like structure of said closure structure while in its larger size over and across the shunt, closing the shunt;

f) allowing said umbrella-like structure of said closure structure to become endothelialized, further closing off the shunt; and

g) ultimately closing off said opening; whereby the shunt is permanently closed by substantially non-invasive or at least limitedly evasive or at least limitedly evasive techniques and without the substantial sutur ing of the shunt as practiced in the prior art.

37. The method of Claim 36 wherein in step "a" said operative means includes an outer catheter having a storage capsule section at its distal end, and wherein in step "c" said closure structure is introduced while stored in said storage capsule, the walls of said storage capsule providing said radial restraint.

38. The method of Claim 37 wherein in step "a" in providing said expansion means there is further included the providing of a second umbrella-like structure having the same claimed features as the first umbrella-like structure for placement on the opposite side of the shunt from said first umbrella-like structure and steps "c" through "d" are each done for said second umbrella-like structure.

Dated this 25th day of March 1975

Aston Ochsner Medical Foundation

I certify that this and the preceding 16 pages are a true and ex act copy of pages 5, 15, 24, 25 & 30 - 42 of the specification originally lodged.



- 4 JUL 1975

J. A. Barnes.

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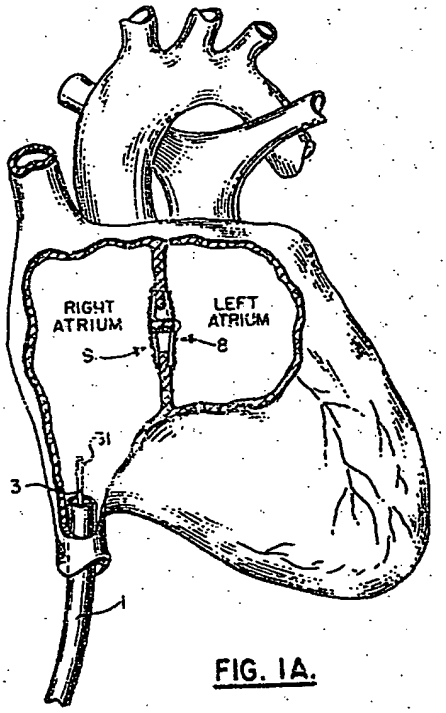



FIG. 1A.

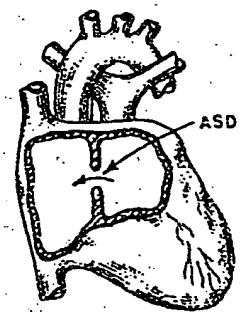



FIG. 1B.

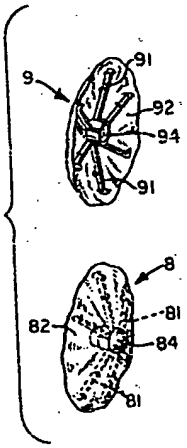



FIG. 1C.

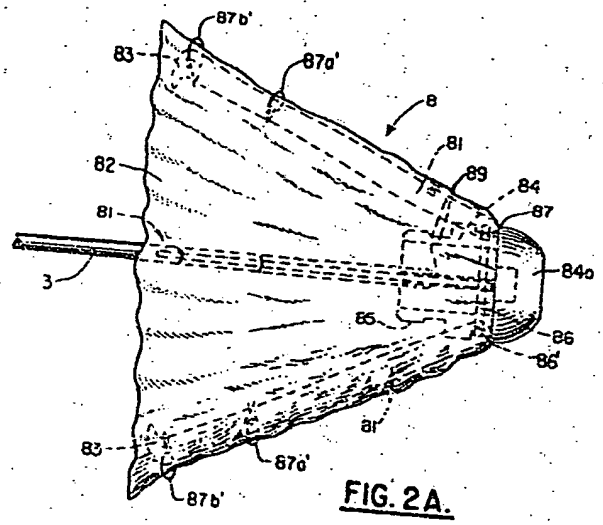



FIG. 2A.

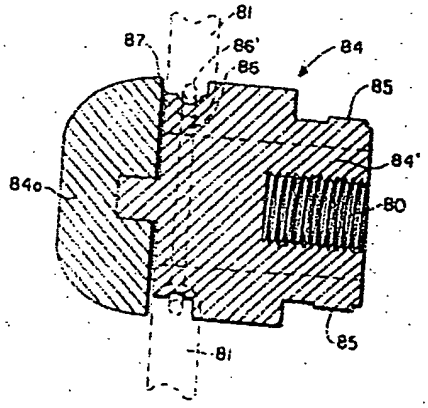



FIG. 2B.

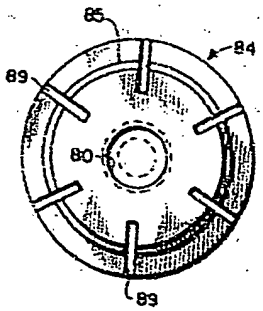



FIG. 2C.

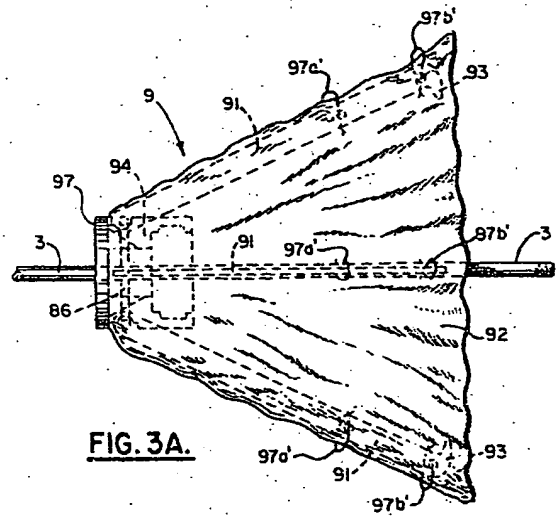



FIG. 3A.

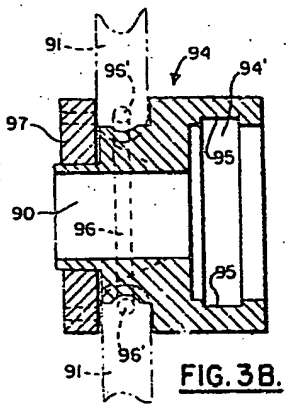



FIG. 3B.

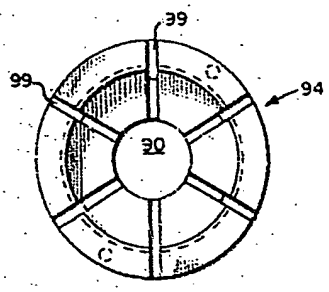



FIG. 3C.

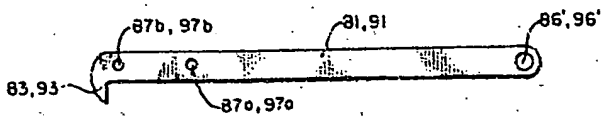



FIG. 4.

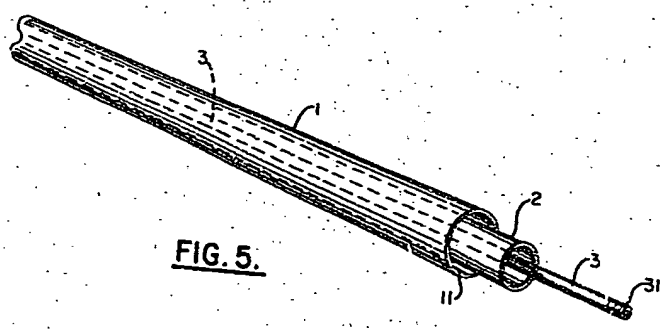



FIG. 5.

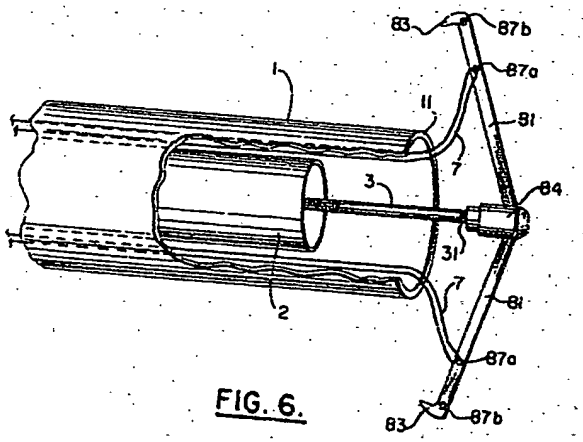



FIG. 6.

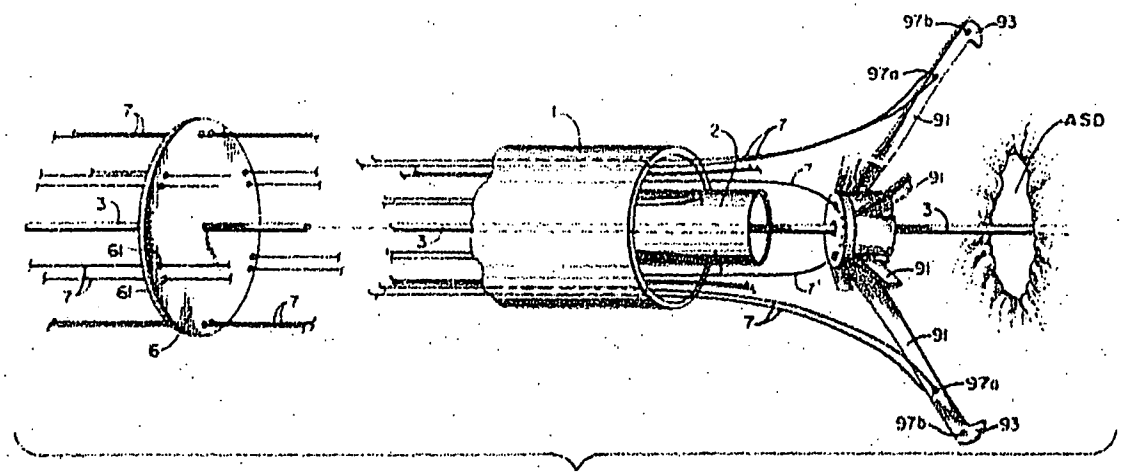



FIG. 7.

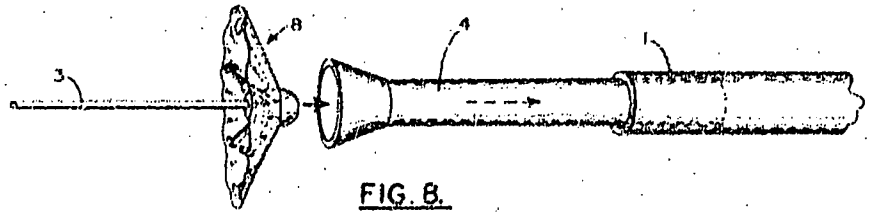



FIG. 8.

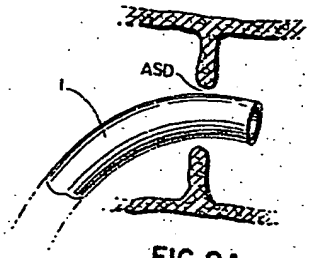



FIG. 9A.

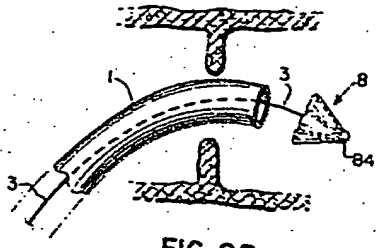



FIG. 9B.

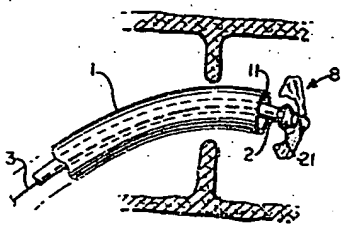



FIG. 9C.

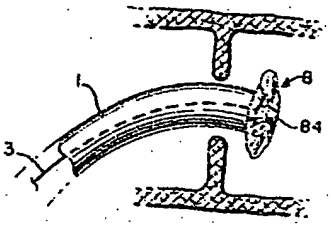



FIG. 9D.

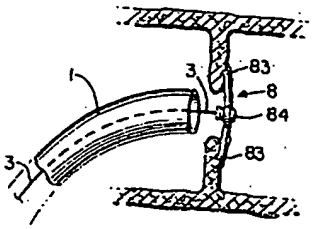



FIG. 9E.

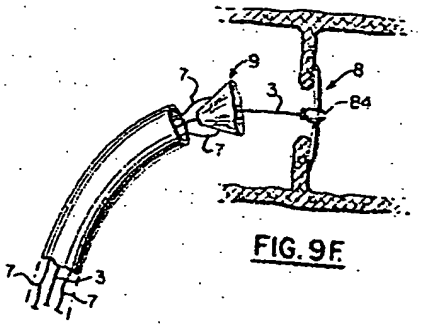



FIG. 9F.

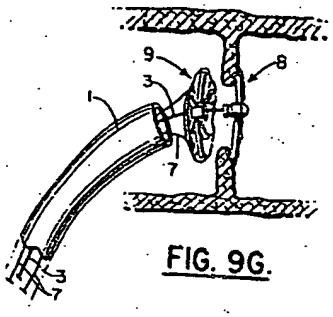



FIG. 9G.

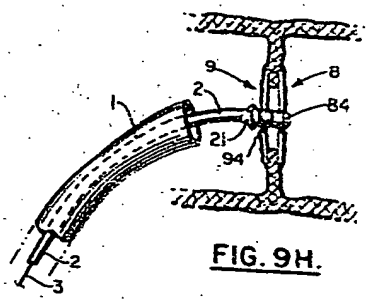



FIG. 9H.

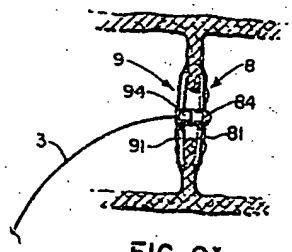



FIG. 9I.

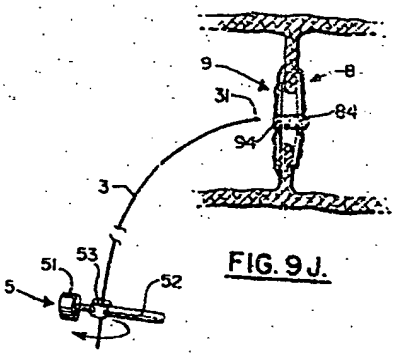



FIG. 9J.

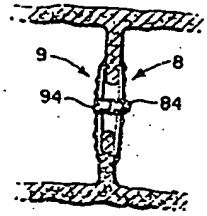



FIG. 9K.

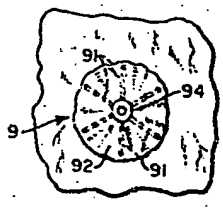



FIG. 10A.

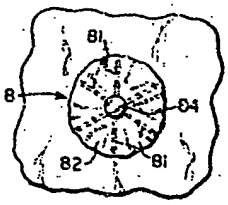



FIG. 10B.

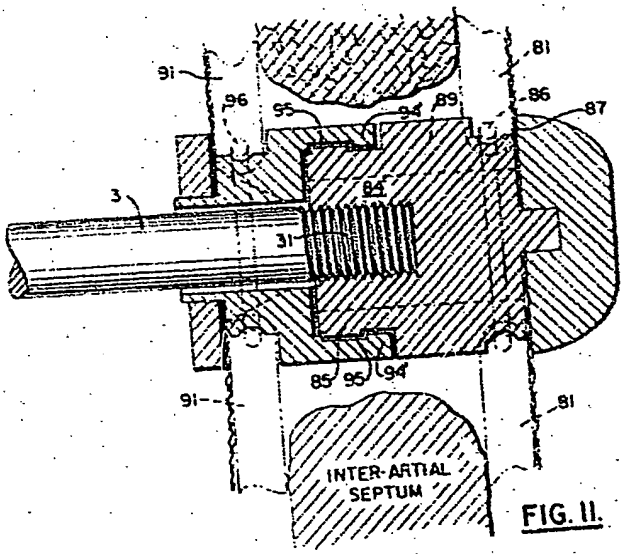



FIG. 11.

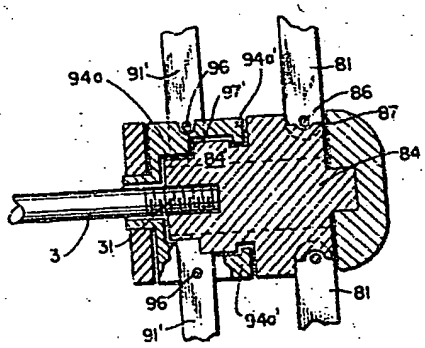



FIG. 12A.

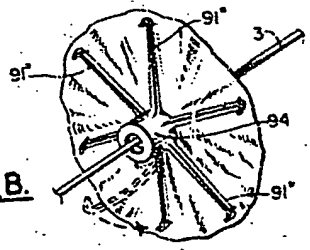



FIG. 12B.

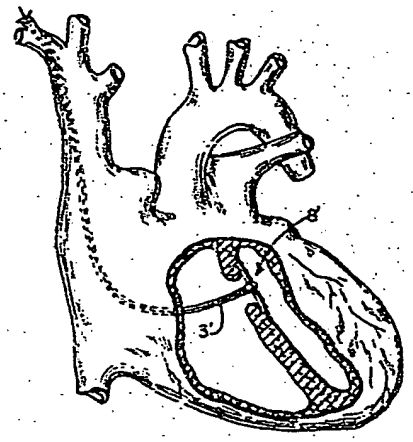



FIG. 13A.

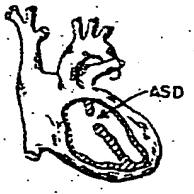



FIG. 13B.


FIG. 13C.

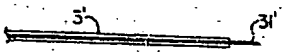



FIG. 13D.

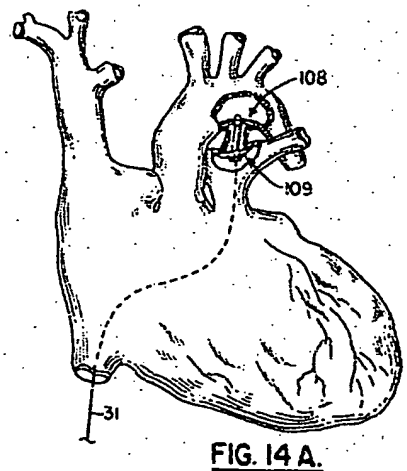



FIG. 14A.


FIG. 14B.

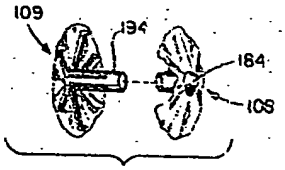



FIG. 14C.

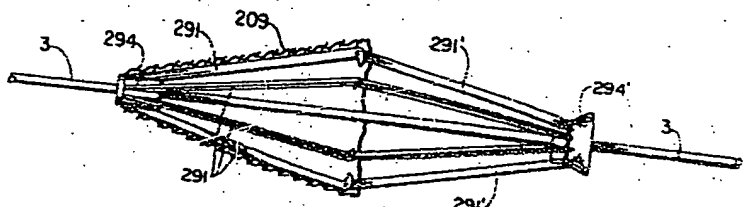



FIG. 15A.

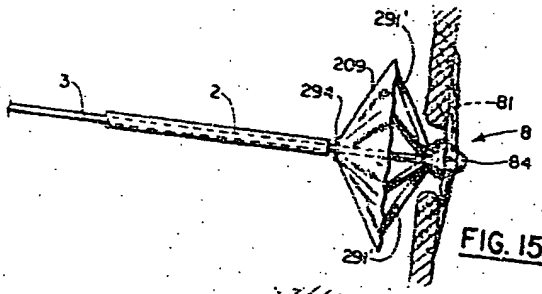



FIG. 15B.

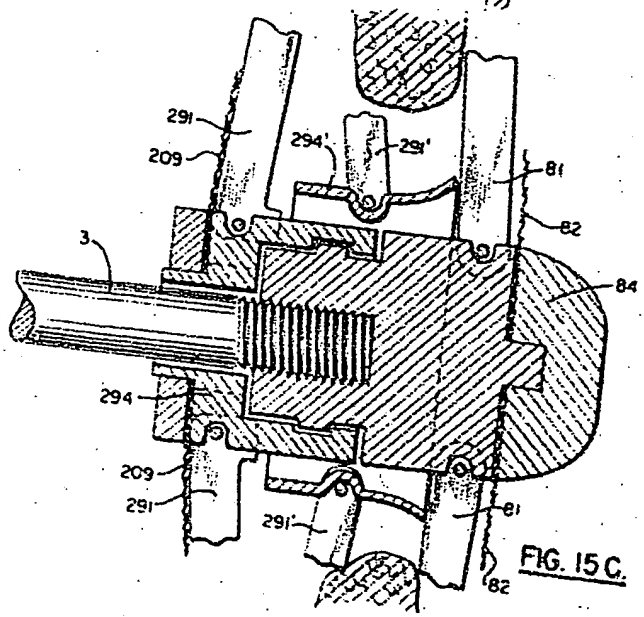
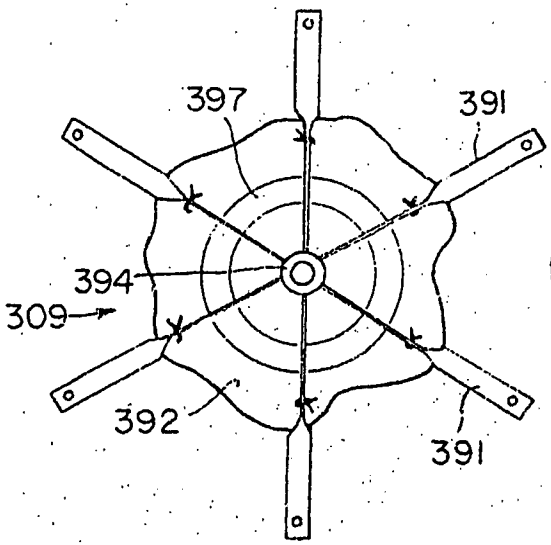
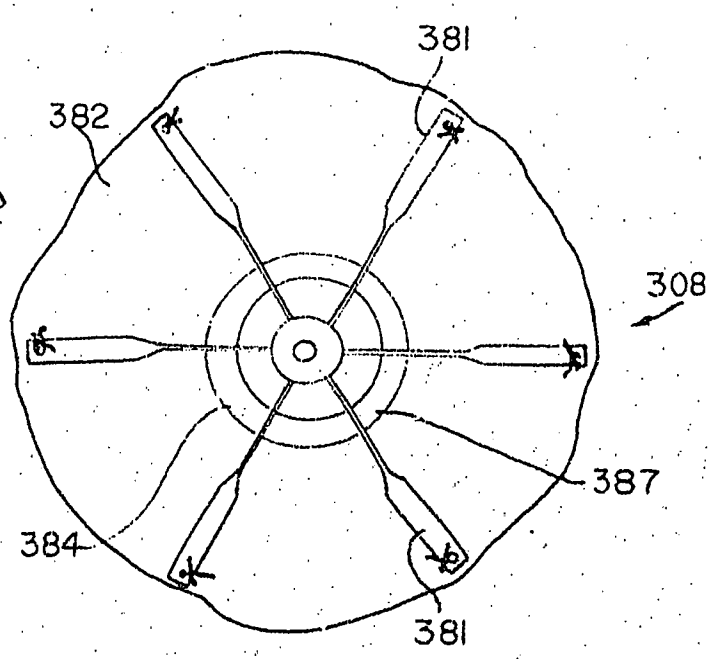



FIG. 15C.



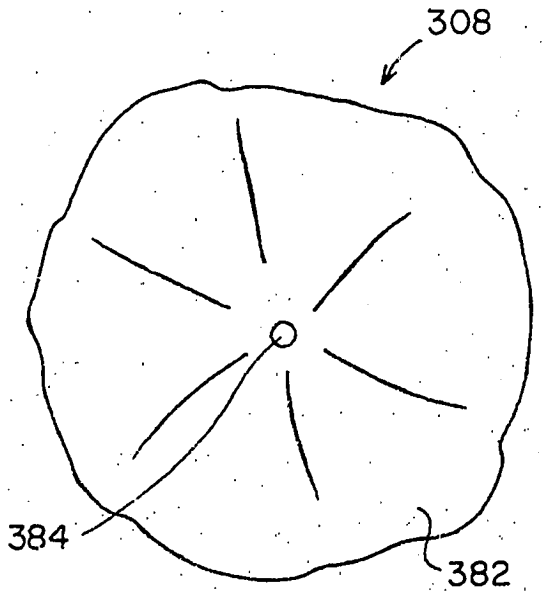

Rt. Atrial Umbrella

FIG. 17A



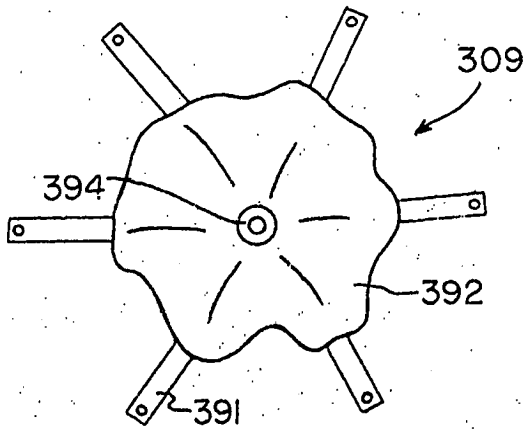

L. Atrial Umbrella

FIG. 16A




L. Atrial Umbrella

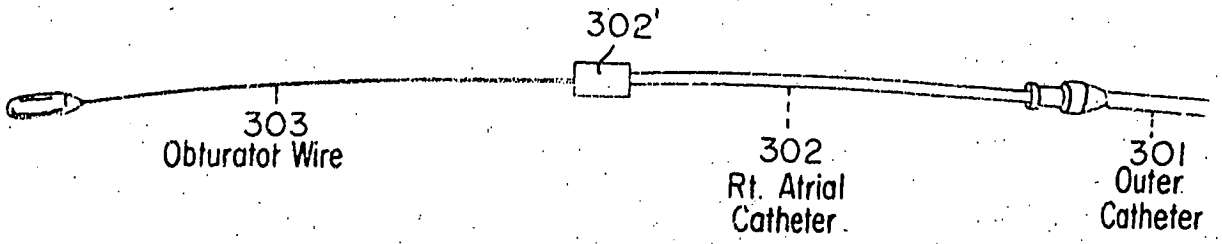
FIG. 16B




Rt. Atrial Umbrella

FIG. 17B

FIG. 18



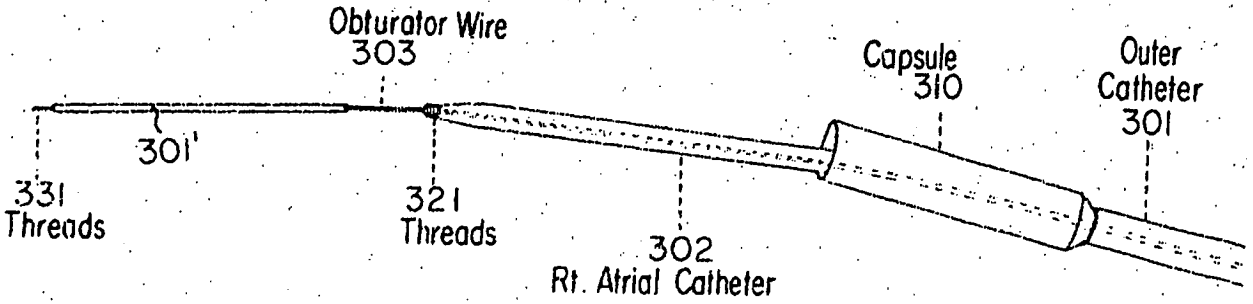




FIG. 19

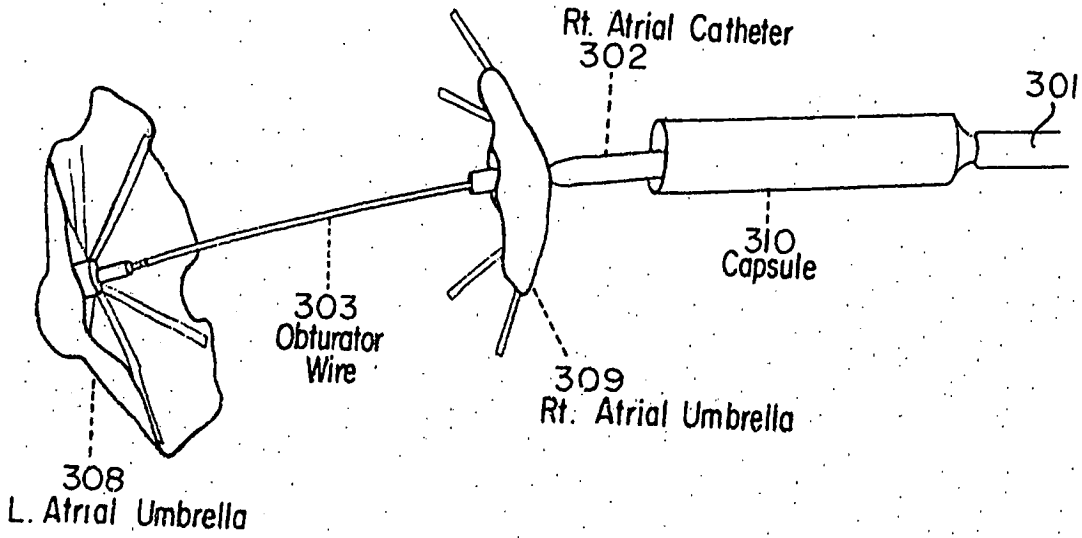

Rt. Atrial Catheter
302
301
310
Capsule
303
Obturator
Wire
309
Rt. Atrial Umbrella
308
L. Atrial Umbrella

FIG. 20